IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF OREGON

MEDFORD DIVISION

ALLEN and LANI MILOVICH,

Plaintiffs,

v.

AZIYO BIOLOGICS, INC. *doing business as Elutia Inc.*, ELUTIA, INC. *formerly known as Aziyo Biologics, Inc.*, MEDTRONIC SOFAMOR DANEK USA, INC., SPINALGRAFT TECHNOLOGIES, LLC, DCI DONOR SERVICES, INC., and NEW MEXICO DONOR SERVICES,

Defendants.

Case No. 1:24-cv-01208-CL

FINDINGS AND RECOMMENDATION

CLARKE, Magistrate Judge.

Allen and Lani Milovich ("Plaintiffs") bring this action against Aziyo Biologics, Inc., Elutia, Inc., Medtronic Sofamor Danek USA, Inc., Spinalgraft Technologies, LLC, DCI Donor Services, Inc., and New Mexico Donor Services (collectively "Defendants"). Before the Court is Defendants' Motion for Partial Dismissal, ECF No. 18. For the reasons below, the Court recommends the Motion to Dismiss be GRANTED.

LEGAL STANDARD

A Rule 12(b)(6) motion to dismiss will be granted where a plaintiff fails to state a claim upon which relief may be granted. Fed. R. Civ. P. 12(b)(6). To state a claim for relief, a pleading must contain "a short and plain statement of the claim showing that the pleader is entitled to

relief." Fed. R. Civ. P. 8(a)(2). It should provide the defendant with fair notice of what the claim is and the grounds upon which it rests. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). While "detailed factual allegations" are not required, "a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009); *Shroyer v. New Cingular Wireless Servs., Inc.*, 622 F.3d 1035, 1041 (9th Cir. 2010). Facial plausibility exists where the factual allegations allow the court to infer a defendant's liability based on the alleged conduct. *Iqbal*, 556 U.S. at 678. A pleading that offers mere "labels and conclusions" is insufficient, as is "a formulaic recitation of the elements." *Id.*

In evaluating a motion to dismiss, the court must accept all allegations of material fact as true and construe those allegations in the light most favorable to the non-moving party. *Odom v. Microsoft Corp.*, 486 F.3d 541, 545 (9th Cir. 2007). The court is "not bound to accept as true a legal conclusion couched as a factual allegation." *Twombly*, 550 U.S. at 555. Nor must a court accept as true "allegations that are merely conclusory, unwarranted deductions of fact, or unreasonable inferences." *Daniels-Hall v. Nat'l Educ. Ass'n*, 629 F.3d 992, 998 (9th Cir. 2010).

BACKGROUND

This personal injury action involves FiberCel. Defendants categorize FiberCel as a Human Cellular and Tissue Based Product (HCT/P), which consists of processed human bone tissue.[1]

Federal regulations define HCT/Ps as "articles containing or consisting of human cells or tissues that are intended for implantation, infusion, or transfer into a human recipient." 21 C.F.R. § 1271.3(d). Per federal regulations, HCT/Ps must be "minimally manipulated," which federal

[1] *See* FiberCel Instructions for Use ("IFU"), https://elutia.com/wp-content/uploads/2020/07/IFU-0021-Rev03-FiberCel.pdf. The parties do not dispute the accuracy or authenticity of this publicly available document. The Court thus takes judicial notice of the FiberCel IFU.

regulations define as processing that does not alter the relevant biological characteristics of the cells or tissues. 21 C.F.R. § 1271.3(f)(2).

FiberCel is made from human tissue consisting of cancellous bone particles with preserved cells, combined with demineralized cortical fiber. Am. Compl. at ¶ 23. FiberCel is "marketed for use in orthopedic and reconstructive bone grafting procedures with the use of autologous bone or other forms of allograft bone or alone as a bone graft." *Id.* at ¶ 26.

Plaintiff underwent cervical spine surgery on April 1, 2021, in which he was implanted with FiberCel allograft allegedly contaminated with tuberculosis. *Id.* at ¶¶ 53-55. Plaintiff alleges that, as a result of the FiberCel implant, he contracted tuberculosis and has been forced to undergo medical treatment to manage the infection. *Id.* at ¶¶ 57-61. Plaintiff alleges that Aziyo developed and manufactured the FiberCel that was implanted during his surgery, which was subsequently sold, marketed, and distributed by defendant Medtronic Sofamor Danek USA, Inc. and SpinalGraft Technologies LLC. *Id.* at ¶¶ 6, 10, 12.

Plaintiff's Complaint asserts claims against Defendants for negligence (First and Fifth Cause of Action), strict liability (Second Cause of Action), breach of implied warranty (Third Cause of Action), breach of express warranty (Fourth Cause of Action), and loss of consortium (Sixth Cause of Action). Defendants argue the strict liability and breach of warranty claims should be dismissed for failure to state a claim upon which relief can be granted because Aziyo is protected from liability under Oregon's blood and tissue shield statute.

DISCUSSION

I. Oregon's Blood and Tissue Shield Statute Bars Strict Liability and Breach of Warranty Claims Relating to FiberCel.

As interpreted by Oregon courts, Oregon's blood and tissue shield statute precludes strict liability and breach of warranty claims for injuries arising from blood or tissue injections,

transfusions, or transplants. The statute does this by declaring that each activity undertaken to provide a blood or tissue injection, transfusion, or transplant "is not a sales transaction."

> 1) The procuring, *processing*, furnishing, distributing, administering or using of *any part of a human body for the purpose of* injecting, transfusing or *transplanting that part into a human body is not a sales transaction* covered by an implied warranty under the Uniform Commercial Code or otherwise.
>
> 2) As used in this section, "part" means organs or parts of organs, *tissues*, eyes or parts of eyes, *bones*, arteries, blood, other fluids and any other portions of a human body.

Or. Rev. Stat. § 97.985 (emphasis added). By its plain language, the statute precludes implied warranty claims. Furthermore, because strict liability and warranties, either implied or express, arise only from sales transactions, it follows that they cannot arise from one of the activities that the statute declares "is not a sales transaction." *See Royer v. Miles Lab'y, Inc.*, 811 P.2d 644, 647 (Or. App. 1991) ("The main focus of [the blood shield statute, formerly numbered ORS § 97.300,] is on declaring that the transactions do not constitute sales. Because strict liability cannot arise without there having been a sale, defendants could not be strictly liable" for plaintiff's injuries stemming from the defendant manufacturer's tainted blood product). In *Royer*, the court noted how "[t]he legislative history [of what is now § 97.985] makes plain *that the legislature intended to preclude liability [for activities described in the statute] without fault, whatever its nature"—whether framed as warranty liability or strict liability in tort. Id.* (emphasis added). Accordingly, activities undertaken to manufacture the blood- or tissue-based products are services, not sales transactions, under the statute, and therefore, the manufacturer was statutorily exempt from strict liability, even though the statute does not expressly mention strict liability. *Id.*; *cf. Brown v. GlaxoSmithKline, LLC*, 523 P.3d 132, 141 (Or. App. 2022), *aff'd sub nom., Providence Health Sys. - Oregon v. Brown*, 548 P.3d 817 (Or. 2024) ("the legislature may . . . express the intent to exclude certain products or sellers from strict liability by declaring

that transactions in such products do not constitute sales, as it did in former ORS 97.300 [what is now § 97.985]") (emphasis omitted).

Additionally, in *Coloplast,* the court applied Oregon's statute to dismiss claims of strict liability and breach of express warranty against the manufacturer of an implanted transvaginal surgical mesh made of human collagen, which the plaintiff alleged had caused several medical complications. *In re Coloplast Corp. Pelvic Support Sys. Prod. Liab. Litig.*, No. 2:13-CV-15065, 2017 WL 6417807, at **3–5. Citing *Royer* the court dismissed the strict liability claim. *See id.* Furthermore, the court determined that "[s]imilarly, the plaintiff's claim for express warranty must also fail" since "[i]t is axiomatic, of course, that breach of express warranty is not available as a cause of action without a sale, because the essence of warranty is a consensual agreement—express or implied—arising from contract. Without a sale under contract, there is no consensual nexus between the parties and thus no warranties may attach." *Id.* at *4 (citation omitted).

Here, like the plaintiffs in *Royer* and *Coloplast*, Plaintiffs claim strict liability and breach of warranty against the manufacturer of a blood- or tissue-based product for damages allegedly arising from the transfusion or transplantation of that product. Specifically, Plaintiffs claim that Aziyo manufactured a unit of the tissue product FiberCel from contaminated tissue and that Plaintiff allegedly contracted tuberculosis after FiberCel was transplanted during a surgical procedure. *See* Compl. at ¶¶ 60-66. Because the Courts in *Royer* and *Coloplast* dismissed similar claims arising under the same statute, the Court here should do the same.

Plaintiffs argue this case is distinguishable from those discussed above. The Court disagrees. Plaintiffs suggest this case is distinguishable from *Royer* because the decision in that case applied to blood and blood derivatives, but it "is not applicable to highly manipulated and manufactured products like FiberCel." ECF No. 19 at p. 11. The Court takes issue with this claim

for two reasons. First, nothing in the opinion of *Royer* indicates the holding should be limited to pure blood and blood derivatives as opposed to more manipulated or manufactured products. Second, even if this distinction were made, it would be irrelevant as courts have consistently found FiberCel within the protections of blood and shield statutes despite its processing (see discussion below).

Plaintiffs also argue this case is distinguishable from *Coloplast*. To start, the Court would like to point out that Plaintiffs are not referring to the same *Coloplast* case as Defendants. The *Coloplast* cases are part of multidistrict litigation. In the case cited by Defendants, Oregon's statute is applied, while in the case cited by Plaintiffs, Ohio's statute is applied. This Court limits its focus to the case cited by Defendants involving Oregon's statute. *Coloplast* involves the same statute, a similar tissue-based product, and the same reasoning that this Court advances. Thus, the Court finds the holding and analysis in *Coloplast* applicable here.

Furthermore, courts in other jurisdictions have applied their state's blood and tissue statute to the very FiberCel material at issue here and determined that attendant claims of strict liability and breach of warranty were barred. For instance, in *Dorota Zydek v. Aziyo Biologics, Inc., et al.*, the United States District Court for the Northern District of Illinois, noted that Illinois' blood and tissue statute, similar to Oregon's statute, defines the processing and distribution of human tissue as the rendition of a service by every person, firm, or corporation participating therein. *See Zydek v. Aziyo Biologics, Inc.*, No. 23 C 3016, 2024 WL 197264, at *2 (N.D. Ill. Jan. 18, 2024). In holding that the Illinois statute barred strict liability and breach of warranty claims against Aziyo, the court determined that, irrespective of the FDA's and NIH's definition of FiberCel as a "product," it was "clear and straightforward" that the Illinois statute applied to FiberCel since it was made from human tissue for transplantation. *Id.* Therefore, the

processing and distribution of FiberCel was a service under the statute, and the court dismissed the plaintiff's strict liability and breach of warranty claims against Aziyo. *Id.* Other courts applying blood and tissue shield statutes to FiberCel claims have followed suit. *See Lokkart v. Aziyo Biologics, Inc.*, No. 2:23-CV-01961-HDV-E, 2024 WL 3057364, at *4 (C.D. Cal. May 29, 2024) (California's blood and tissue shield statute barred plaintiff's strict liability and breach of implied warranty claims against Aziyo as to FiberCel); *Sherrill v. SpinalGraft Techs., LLC*, No. 5:21-CV-00172-KDB-SCR, 2024 WL 1979452, at *2 (W.D. N.C. May 3, 2024) (the blood and tissue shield statute in North Carolina [a state that does not recognize strict liability claims] barred breach of warranty claims against Aziyo as to FiberCel).

To the extent that Plaintiff's Complaint attempts to plead around Oregon's blood and tissue statute by asserting that human tissue is combined with other materials to make FiberCel (*see e.g.*, Compl. ¶¶ 24, 26), courts in the FiberCel cases cited above have already rejected that contention. In *Sherrill*, the court rejected the plaintiffs' argument that processing bone tissue into FiberCel renders FiberCel a "product" outside the scope of the statute's protection and held that the processing and sale of FiberCel constituted a "service," because North Carolina's law "protects from liability any participating person or institution involved in the 'processing' of human tissues, including bones, as long as the ultimate purpose is to inject, transfuse, or transplant that tissue into the human body." *Sherrill*, 2024 WL 1979452 at *2-3. In *Lokkart*, the court noted, "[Plaintiffs] attempt to sidestep their own allegations cannot be squared with the plain language of the statute." *Lokkart*, 2024 WL 3057364 at *3. The Court observed that the inclusion of "processing" within California's blood and tissue shield statute contemplated that the processing or altering of human tissue into an allograft product did not remove FiberCel from the definition of "human tissue." *Id.* The court also noted that FiberCel's status as an HCT/P

required that FiberCel be "minimally manipulated" and subjected to "processing that does not alter the relevant biological characteristics of the cells or tissues." *Id.* As the court ultimately stated, "[g]iven this standard, the Court must reject [Plaintiffs'] hypothetical argument that FiberCel no longer qualifies as 'a group of [human] cells.'" *Id.* (brackets around "human" in original).

This Court, for the reasons cited above, does not believe additional discovery would change the outcome of its ruling on this motion. Thus, Defendants' motion should be granted.

II. Oregon's Blood and Tissue Shield Reflects a Nationwide Public Policy Rationale in Favor of Protecting Human Tissue Products from Strict Liability and Breach of Warranty Claims.

Oregon's blood and tissue shield statute mirrors similar blood and tissue shield statutes which have been enacted in virtually every state. *See, e.g., Palermo v. LifeLink Found., Inc.*, 152 So.3d 1099, 1103 (Miss. 2014) (noting that only New Jersey and Vermont lack such a statute). The court in *Coloplast* also noted that there is a "nationwide policy against applying strict liability to the distribution of human tissue." *In re Coloplast*, 2017 WL 6417807 at *4.

Decisions in the FiberCel cases cited in the section above clearly reflect the public policy rationale which underlies not only Oregon's blood and tissue shield statute, but similar blood and tissue shield statutes across the country: the availability of human blood and tissue for therapeutic purposes should be encouraged by protecting the procurement, processing, and distribution of blood and tissue from no-fault legal liabilities. As the California Court of Appeals noted in *Cryolife, Inc. v. Superior Court*:

> [L]egislatures have determined that the production and use of human blood *and its derivatives* for therapeutic purposes should be encouraged; and for this purpose those who provide these products, and who themselves are free from fault, should not be required to bear the economic loss which might otherwise be imposed under the rules of strict liability which are applicable to sellers of commercial products generally.

110 Cal. App. 4th 1145, 1156 (2003) (holding that the same state interests protect the sale of human musculoskeletal tissue) (emphasis in original).

Language in an Illinois statute demonstrates the public policy rationale underlying the statutory exemption of no-fault liability claims for blood and tissue products:

> The availability of scientific knowledge, skills and materials for the purpose of injecting, transfusing, or transplanting human whole blood, plasma, blood products, blood derivatives and . . . other human tissue is important to the health and welfare of the people of this State. The imposition of legal liability without fault upon the persons and organizations engaged in such scientific procedures inhibits the exercise of sound medical judgment and restricts the availability of important scientific knowledge, skills, and materials.

745 Ill. Comp. Stat. 40/1; *see also Poole v. Alpha Therapeutic Corp.*, 698 F. Supp. 1367, 1370 (N.D. Ill. 1988) (recognizing numerous cases which "demonstrate . . . nationwide acceptance" of the policy rationale).

Under this same rationale, courts nationwide have barred liability theories against blood and tissue suppliers. As the District of Utah noted in *Condos v. Musculoskeletal Transplant Foundation*, "[n]o court has ever applied strict liability to the distribution of human tissue." 208F. Supp. 2d 1226, 1229 (D. Utah 2002); *see also Palermo v. LifeLink Found., Inc.*, 152 So.3d 1177, 1181 (Miss. Ct. App. 2014), aff'd, 152 So.3d 1099 (Miss. 2014) ("The case law reflects that there is a nationwide antipathy over applying products-liability or strict-liability concepts to body parts such as blood and tissue").

Furthermore, Oregon's blood and tissue shield statue applies to both nonprofit and for-profit organizations. Plaintiffs argue the statute applies only to nonprofit entities, thus rendering it inapplicable here. In support of this claim, Plaintiffs cite to several cases from other states where the applicable blood and tissue shield statues did not apply to for-profit organizations. These cases, however, have no bearing on the application of the statute in this case. The Oregon Court of Appeals has explicitly rejected the idea that Oregon's blood and tissue shield statute

applies only to nonprofit organizations. *Royer*, 811 P.2d at 647 ("Plaintiff argues that, if we hold that the statute precludes strict liability, we should limit that holding to nonprofit organizations, thus keeping defendant Miles potentially liable. *There is no basis in the statute for that distinction.*") (emphasis added)).

The explicit legislative intent of the Statute was to "ensure that the blood and tissues . . . should not be considered to be within the concept of a thing to be sold" and to shield against strict liability arising out of the procurement, processing, distribution, or use of human tissue for purposes of transplant *Id.* at 114, 117 (discussing legislative history behind enactment of Oregon's blood and tissue shield statute). Plaintiffs now seek to undercut that intent by inserting restrictions to the application of the Statute which do not exist within the Statute's plain language or its legislative history. This Court will not rewrite a law the Legislature drafted and "passed without any substantial controversy." *Id.* at 117.

III. Even if FiberCel were a "medical device," Plaintiffs' strict liability claims are still barred by Oregon law.

Even if this Court were to accept Plaintiffs' contention that "processing" human tissue renders that tissue a "designed, developed, manufactured, branded and marketed medical product," Plaintiffs' strict liability claims are still barred under Oregon law. Oregon has adopted the Restatement (Second) of Torts, § 402A Comment k, which precludes liability for manufacturers of prescription medical devices under a theory of strict products liability. Or. Rev. Stat. § 30.920(3) (specifically adopting the Restatement (Second) of Torts § 402A, Comments a through m for product liability cases); *Senn v. Merrell-Dow Pharmaceuticals, Inc.*, 751 P.2d 215, 217 (Or. 1988) (ORS 30.920 "adopts Restatement (Second) of Torts § 402A and its attendant comments as the law of the state"). Comment k states:

> *There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use.* These are especially common in the field of drugs. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve. *Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous. The same is true of many other drugs, vaccines, and the like, many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician.* It is also true in particular of many new or experimental drugs as to which, because of lack of time and opportunity for sufficient medical experience, there can be no assurance of safety, or perhaps even of purity of ingredients, but such experience as there is justifies the marketing and use of the drug notwithstanding a medically recognizable risk. *The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.*

Restatement (Second) of Torts, § 402A Comment k (emphasis added).

Comment k exempts "unavoidably unsafe products," like prescription medical devices, from strict liability claims based on the recognition that such products have inherent risks that are incapable of being designed away. Because it contains live human tissue, the risk of disease transmission inherent to FiberCel—or any other live tissue product—can never be designed away. (*See* ECF No. 19 at p. 8 (citing 6A American Law of Torts § 18:443 for the premise that "there are not now, and realistically there may never be, tests that can guarantee with absolute certainty that the donated blood is uncontaminated with certain viruses or other contaminants.")). Indeed, the FiberCel IFU expressly warns that "[c]urrent technologies may not preclude the transmission of infectious agents or disease, including hepatitis and HIV." *See* IFU.

If—as Plaintiffs allege in their Amended Complaint—FiberCel is made from human tissue, Plaintiffs' claims are barred by the blood and tissue shield statute. If—as Plaintiffs allege in their answering brief, ECF No. 19—FiberCel is a medical device, Plaintiffs' claims are barred

by Oreogn's adoption of Section 402A. Thus, while the Court agrees with Aziyo that FiberCel is made from human tissue under the blood and tissue shield statute, even if FiberCel were a "medical device," Plaintiffs' strict liability and breach of warranty claims would still warrant dismissal under Oregon law.

RECOMMENDATION

For the reasons above, Defendants' Motion for Partial Dismissal, ECF No. 18, should be GRANTED. Plaintiff's strict liability and breach of warranty claims should be dismissed.

This Findings and Recommendation will be referred to a district judge. Objections to this Findings and Recommendation, if any, are due fourteen (14) days from today's date. If objections are filed, any response is due fourteen (14) days from the date of the objections. *See* Fed. R. Civ. P. 72, 6. Parties are advised that the failure to file objections within the specified time may waive the right to appeal the district court's order. *Martinez v. Ylst*, 951 F.2d 1153 (9th Cir. 1991). This Recommendation is not an order that is immediately appealable to the Ninth Circuit Court of Appeals. Any notice of appeal pursuant to Federal Rule of Appellate Procedure 4(a)(1) should not be filed until entry of the district court's judgment or appealable order.

DATED this 24 day of February, 2025.

MARK D. CLARKE
United States Magistrate Judge